UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

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ASSOCIATION FOR MOLECULAR PATHOLOGY, ET AL.,

Plaintiffs,

09 Civ. 4515

-against-

OPINION

UNITED STATES PATENT AND TRADEMARK OFFICE, ET AL.,

Defendants.

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Sweet, D.J.

In this action the Plaintiffs challenge certain patent claims granted to defendants Myriad Genetics and the Directors[1] of the University of Utah Research Foundation ("UURF") (collectively, "Myriad") by defendant United States Patent and Trademark Office ("USPTO") (collectively, the "Defendants"). The identified patent claims (the "patents-in-suit" or the "claims-in-suit") cover two human genes known as *BRCA1* and *BRCA2* (collectively, "*BRCA1/2*" or the "*BRCA* genes"). Compl. ¶¶ 37, 55-80. The claims-in-suit also cover certain mutations in those genes, the mental act of comparing different forms of the *BRCA* genes, and the correlations between certain genetic mutations and an increased risk of breast and/or ovarian cancer. Id.

The Plaintiffs allege that these patents are unlawful under each of (1) the Patent Act, 35 U.S.C. § 101 (1952), (2) Article I, Section 8, Clause 8 of the United States Constitution, and (3) the First and Fourteenth Amendments because they cover products of nature, laws of

[1] Defendants Lorris Betz, Roger Boyer, Jack Brittan, Arnold B. Combe, Raymond Gesteland, James U. Jenson, John Kendall Morris, Thomas Parks, David W. Pershing, and Michael K. Young. For purposes of this opinion, they will be referred to as the "Directors" or the "UURF Directors."

nature and/or natural phenomena, and abstract ideas or basic human knowledge or thought. Compl. ¶ 102.

The Defendants now move, pursuant to Rules 12(b)(1), (b)(2), and (b)(6), Fed. R. Civ. P., to dismiss Plaintiffs' complaint (the "Complaint") for lack of subject matter jurisdiction, lack of personal jurisdiction, and failure to state a claim.

This action is unique in the identity of the parties, the scope and significance of the issues presented, and the consequences of the remedy sought. The Plaintiffs in this action comprise a broad range of parties, including researchers, genetic counselors, medical and/or advocacy organizations, and women facing the threat of breast cancer or who are in the midst of their struggle with the illness. The challenges to the patents-in-suit raise questions of difficult legal dimensions concerning constitutional protections over the information that serves as our genetic identities and the need to adopt policies that promote scientific innovation in biomedical research. The widespread use of gene sequence information as the foundation for biomedical research means that resolution of these issues will have far-reaching implications, not only

for gene-based health care and the health of millions of women facing the specter of breast cancer, but also for the future course of biomedical research.

Based on the conclusions set forth below, the motions to dismiss are denied.

I. PRIOR PROCEEDINGS

The Complaint in this action was filed on May 12, 2009.

The Plaintiffs moved for summary judgment pursuant to Rule 56, Fed. R. Civ. P., on August 26, 2009.

Defendants' motion to dismiss and Plaintiffs' motion for jurisdictional discovery[2] were heard and marked fully submitted on September 30, 2009, and Plaintiffs'

[2] Defendants' motion to dismiss incorporates, by reference, challenges to the exercise of personal jurisdiction over the Directors raised in Defendants' opposition to Plaintiffs' motion for jurisdictional discovery. Consequently, the arguments concerning personal jurisdiction set forth by the parties in connection with Plaintiffs' motion for jurisdictional discovery will be considered here.

motion for summary judgment was stayed pending resolution of Defendants' motion to dismiss.

II. THE COMPLAINT AND THE AFFIDAVITS

The following allegations, taken from the Complaint and the affidavits submitted by the parties in connection with Defendants' motion to dismiss, are accepted as true for the purpose of resolving the motions to dismiss.

A. The Plaintiffs

Plaintiff the Association for Molecular Pathology ("AMP") is a not-for profit scientific society dedicated to the advancement, practice, and science of clinical molecular laboratory medicine and translational research based on the applications of genomics and proteomics. AMP members participate in basic and translational research aimed at broadening the understanding of gene/protein structure and function, disease processes, and molecular diagnostics, and provide clinical medical services for

patients, including diagnosis of breast cancer. Compl. ¶ 7.

Plaintiff the American College of Medical Genetics ("ACMG") is a non-profit organization of clinical and laboratory geneticists seeking to improve health through the practice of medical genetics. AMCG strives to 1) promote excellence in medical genetics practice and the integration of translational research into practice; 2) promote and provide medical genetics education; 3) increase access to medical genetics services and integrate genetics into patient care; and 4) advocate for and represent providers of medical genetics services and their patients. Compl. ¶ 8.

Plaintiff the American Society for Clinical Pathology ("ASCP") is the largest and oldest organization representing pathologists and laboratory professionals. ASCP members design and interpret the tests that detect disease, predict outcome, and determine the appropriate therapy for the patient. Compl. ¶ 9.

Plaintiff the College of American Pathologists ("CAP") is a national medical society representing board-

certified pathologists and pathologists in training who practice anatomic pathology and laboratory medicine worldwide. The CAP is an advocate of high-quality and cost-effective medical care. Compl. ¶ 10.

The affidavits submitted by the Plaintiffs state that members of AMP, ACMG, ASCP, and CAP are ready, willing, and able to engage in research and clinical practice involving the *BRCA1/2* genes if the patents-in-suit were to be invalidated. For example, Madhuri Hegde, Ph.D. ("Dr. Hegde"), is a member of AMP and ACMG and serves as an Associate Professor in the Department of Human Genetics at Emory University School of Medicine, Adjunct Assistant Professor at the University of Texas M.D. Anderson Cancer Center, and Senior Laboratory Director at the Emory Genetics Laboratory. He currently conducts research on human genes in addition to supervising one of the largest and most technologically advanced clinical laboratories in the country. The laboratory sequences and analyzes approximately sixty genes every day for sequence variants and their clinical significance. Dr. Hegde has personally sequenced the *BRCA1/2* genes while at the Auckland Hospital in New Zealand, and his lab would begin sequencing an analyzing *BRCA1/2* genes for clinically significant variants

within weeks if the patents-in-suit were invalidated. Hegde Decl. ¶¶ 3-12.[3]

Roger Hubbard, Ph.D. ("Dr. Hubbard"), a member of ASCP, is the President and Chief Executive Officer, Molecular Pathology Laboratory Network, Inc. ("MPLN"), and an Adjunct Associate Professor at the University of Tennessee Medical Center/Knoxville, Department of Pathology. MPLN offers molecular diagnostics and cytogenetic testing services that target hematological malignancies, oncology, and medical diseases. MPLN currently sequences genes and has the personnel, experience and equipment to analyze the *BRCA* genes. They currently receive inquiries every few weeks from a hospital or laboratory asking them to analyze the BRCA genes, but they do not do so as solely because of the patents-in-suit. If the patents-in-suit were to be invalidated, Dr. Hubbard and MPLN would immediately consider doing *BRCA1/2* testing in their laboratory. Hubbard ¶¶ 1-4, 6, 8-9.

Jeffrey Kant, M.D., Ph.D. ("Dr. Kant"), a member of AMP and CAP, is the Director of the Division of

[3] For purposes of this opinion, references to the parties' declarations will be in the format [Declarant name] ¶ [paragraph number].

Molecular Diagnostics in the Department of Pathology at the University of Pittsburgh Medical Center and a Professor Pathology and Human Genetics at the University of Pittsburgh. As part of his responsibilities, he supervises a clinical laboratory that analyzes human genes and is experienced in sequencing and analyzing genes for inherited diseases. His laboratory currently tests nine genes, including five related to hereditary predisposition for cancer. His laboratory was asked in the late 1990s to engage in the sequencing and analysis of *BRCA1/2*, but declined to do so because of the patents-in-suit. If the patents-in-suit were to be invalidated, Dr. Kant would immediately consider doing full gene testing for the *BRCA* genes. Kant ¶¶ 1-2, 4-6.

Plaintiff Haig Kazazian, Jr., M.D. ("Dr. Kazazian"), is the Seymour Gray Professor of Molecular Medicine in Genetics in the Department of Genetics at the University of Pennsylvania School of Medicine. He is the previous chair of the Department. Kazazian ¶ 1, 2. Plaintiff Arupa Ganguly, Ph.D. ("Dr. Ganguly"), is an Associate Professor in the Department of Genetics at the Hospital of the University of Pennsylvania. Ganguly ¶ 1. Drs. Kazazian and Ganguly have served as co-Directors of

the University of Pennsylvania Genetic Diagnostic Laboratory ("GDL") since 1995. Kazazian ¶ 3; Ganguly ¶ 2. The GDL provides state-of-the-art DNA-based diagnostic testing for a variety of genetic conditions and diseases, as well as prenatal and predictive testing and genetic counseling services. Kazazian ¶ 3. Starting in 1996, the GDL was providing *BRCA1* genetic testing services to approximately 500 women per year. Id. ¶ 4. By late 1996, the GDL had designed and provided a similar test for the *BRCA2* gene. Id. Following Dr. Kazazian's and the University of Pennsylvania's receipt of a series of cease-and-desist letters from Myriad in 1998 and 1999, described infra, the GDL ceased its *BRCA1/2* genetic testing services. Id. ¶¶ 5-7; Ganguly ¶¶ 4-10. If the patents-in-suit were to be invalidated, the GDL possesses the technological capability necessary to begin performing *BRCA1/2* testing again within a matter of weeks, and Drs. Ganguly and Kazazian have the desire to consider doing so. Kazazian ¶ 11; Ganguly ¶ 14.

Plaintiff Wendy Chung, M.D., Ph.D. ("Dr. Chung"), is the Herbert Irving Professor of Pediatrics and Medicine in the Division of Molecular Genetics at Columbia University and is the Director of Clinical Genetics and

Director of Clinical Oncogenetics. She is also a member of ACMG. Dr. Chung is a human geneticist whose current research includes research on the *BRCA* genes, for which she has received grants of over $1 million. Dr. Chung is a co-investigator of the Breast Cancer Family Registry, funded by the National Cancer Institute of the National Institute of Health. The goal of the Registry is to collect and study families with multiple cases of breast and/or ovarian cancer and to study genetic and environmental factors influencing cancer susceptibility and clinical outcomes. As part of her research, Dr. Chung's lab sequences human genes, including the *BRCA1/2* genes of research subjects to determine whether there exist alterations in the gene sequences and investigate their clinical significance. Because of the patents-in-suit, Dr. Chung does not tell the research subjects in her studies the results of the analysis of their *BRCA* genes. Dr. Chung's clinical diagnostic laboratory at Columbia University sends samples to Myriad for any analysis of *BRCA1/2* in order to tell the subjects the results and use the results clinically. It does not do *BRCA* testing on its own because of the patents-in-suit. If the patents-in-suit were to be invalidated, Dr. Chung would begin clinical testing of *BRCA1/2* immediately. Her clinical laboratory has the personnel,

expertise to do various forms of *BRCA1/2* sequencing and would be able to offer genetic testing that is more comprehensive than the testing currently offered by Myriad. Chung Decl. ¶ 1, 4, 8-9, 11-14, 16-18.

Plaintiff Harry Ostrer, M.D. ("Dr. Ostrer"), is a Professor of Pediatrics, Pathology and Medicine, Director of the Human Genetics Program in the Department of Pediatrics at the New York University ("NYU") Langone Medical Center, and a member of ACMG. As Director of the Human Genetics Program, Dr. Ostrer helped establish the Molecular Genetics Laboratory ("MGL") at the NYU Langone Medical Center, one of the largest academic genetic testing laboratories in the United States. Dr. Ostrer's work through the MGL has focused on understanding the genetic basis of development and disease, including genetic susceptibility to breast cancer. Dr. Ostrer is actively engaged in identifying genes that convey the risk of breast cancer and may mitigate the effects of mutations in *BRCA1/2*. His laboratory has the ability to evaluate *BRCA1/2* gene sequences, including in custom-designed tests that may be more cost-effective than Myriad's current offerings. However, because of Myriad's assertions of the patents-in-suit, Dr. Ostrer sends all of his patient

samples to Myriad for *BRCA1/2* analysis. If the patents-in-suit were to be invalidated, Dr. Ostrer would immediately begin clinical sequencing of the *BRCA1/2* genes. His laboratory possesses all of the personnel, expertise, and facilities necessary to do various types of sequencing of the *BRCA1/2* genes, including full sequencing, detection of deletions and rearrangements, and searches for large rearrangements that Myriad currently does not offer as a service. If the patents-in-suit were to be invalidated, Dr. Ostrer would also tell patients involved in his current research program the results of their *BRCA1/2*-related genetic screening. Ostrer Decl. ¶¶ 1-5; 8-10.

Plaintiff David Ledbetter, Ph.D. ("Dr. Ledbetter"), is the Robert W. Woodruff Professor of Human Genetics and Director of the Division of Medical Genetics at the Emory University School of Medicine. He is also a diplomat of the American Board of Medical Genetics (Clinical Cytogenetics) and a Founding Fellow of the ACMG. He has previously served as the Director of the Kleberg Cytogenetics Laboratory at Baylor College of Medicine and in the Senior Executive Service of the federal government as Branch Chief of the Diagnostic Development Branch at the National Center for Human Genome Research (now the National

Human Genome Research Institute). He was also the founding Chair of the Department of Human Genetics at the University of Chicago where he held the Marjorie I. and Bernard A. Mitchell Professor of Human Genetics. As Director of the Division of Medical Genetics, Dr. Ledbetter is responsible for very large genetic testing laboratories at the Emory University School of Medicine which provide clinical testing services for patients and families with genetic diseases, including biochemical, cytogenetics, and molecular genetics testing. The genetic testing laboratory utilizes state-of-the-art technology and has the personnel, experience, expertise, and facilities necessary to conduct comprehensive mutation analysis (including full gene sequencing and high-resolution deletion/duplication analysis) of any human gene, including the *BRCA* genes. If the patents-in-suit were to be invalidated, Dr. Ledbetter would begin offering comprehensive *BRCA1/2* testing and would likely have an operational program within one month's time. Ledbetter Decl. ¶¶ 1, 3-4, 8-10, 18.

Plaintiff Stephen T. Warren, Ph.D. ("Dr. Warren"), is the William Patterson Timmie Professor of Human Genetics and Professor of Biochemistry and Professor of Pediatrics at Emory University as well as a past

President of the American Society of Human Genetics. He personally supervises genetic research at Emory University and is also responsible for the Emory Genetics Laboratory. Dr. Warren is ready, willing, and able to being *BRCA1/2* genetic testing if the patents-in-suit were to be invalidated. Compl. ¶ 17.

Plaintiff Ellen Matloff, M.S. ("Ms. Matloff"), is Director of the Yale Cancer Genetic Counseling Program and a Research Scientist in the Department of Genetics at the Yale University School of Medicine. Ms. Matloff advises women on the desirability of obtaining an analysis of their genes to determine if the women have the genetic mutations that correlate with an increased risk of breast and/or ovarian cancer. Ms. Matloff also arranges for such genetic analysis and advises women on the significance of the results. As a result of the patents-in-suit, Ms. Matloff is currently required to utilize Myriad's testing services for analysis of *BRCA1/2*. If the patents-in-suit were to be invalidated, Ms. Matloff would immediately begin sending samples from women who are appropriate candidates for *BRCA* gene analysis to laboratories other than Myriad, such as the laboratories of Drs. Chung, Ledbetter, and Ostrer, for

gene sequencing as well as large rearrangement testing. Matloff Decl. ¶¶ 1, 4, 10-15.

Plaintiff Elsa W. Reich, M.S. ("Ms. Reich"), is a Professor of Pediatrics in the Human Genetics Program at the NYU School of Medicine Department of Pediatrics, where she has served as a genetic counselor since 1974. Ms. Reich provides risk assessment and information to women and men about their risk of having a heritable form of cancer and advises them on the potential utility of obtaining an analysis of their genes to determine if they have genetic mutations that correlate with an increased risk of developing breast cancer, ovarian cancer, or other malignancies. The genes of most interest to be analyzed are the *BRCA1/2* genes. If a patient requests this testing, Ms. Reich sends samples to Myriad and explains the results to the patient. If the patents-in-suit were to be invalidated, Ms. Reich would immediately begin sending samples, including ones previously tested by Myriad, to other laboratories, such as those of Drs. Chung, Ostrer, and Ledbetter for *BRCA1/2* testing. Reich Decl. ¶¶ 1-3, 7-9, 14-15.

Plaintiff Breast Cancer Action ("BCA") is a national organization of approximately 30,000 members based in San Francisco, California that works with researchers to encourage innovative approaches to unresolved issues in breast cancer. Members of Breast Cancer Action have had their *BRCA* genes analyzed or sought analysis to determine if they have genetic mutations that correlate with an increased risk of breast and/or ovarian cancer. In some instances, members have been unable to obtain testing at a laboratory of their choice or choose to be tested at a laboratory that would share data with researchers. In other instances, members have been unable to obtain *BRCA1/2* genetic testing because of the high cost of the test. Members have also received ambiguous genetic test results from Myriad that show they have a genetic variant of uncertain significance, but have been unable to obtaining testing from a second laboratory. BCA staff and volunteers also provide information to members of the public about genetic analysis but have been unable to refer patients to labs other than Myriad. If the patents-in-suit were to be invalidated, BCA and its members would immediately begin utilizing other alternatives to Myriad's *BRCA1/2* testing services in addition to publicizing the existence of such

alternatives, such as the laboratories of Drs. Chung and Ostrer. Compl. ¶ 19; Brenner Decl. ¶¶ 2-3, 7, 9.

Plaintiff Boston Women's Health Book Collective ("BWHBC"), doing business as Our Bodies Ourselves ("OBOS"), is a women's health education, advocacy, and consulting organization that seeks to educate women about health, sexuality, and reproduction. OBOS staff provides information to members of the public about genetic analysis, but does not, as a result of the patents-in-suit, refer their readers to or publicize genetic testing services at, laboratories other than Myriad. BWHC also does not advocate for researchers and clinicians to perform *BRCA* testing as a result of the patents-in-suit. If the patents-in-suit were to be invalidated, BWHBC and OBOS are ready, willing, and able to provide information about testing options offered by labs other than Myriad and would directly benefit from any increased research on *BRCA1/2*. Compl. ¶ 20; Norsigian Decl. ¶¶ 2-3.

Plaintiff Lisbeth Ceriani ("Ms. Ceriani") is a 43-year-old single mother who was diagnosed with cancer in both breasts in May 2008. Ms. Ceriani's oncologist and genetic counselor recommended that she obtain *BRCA1/2*

genetic testing to determine whether she should consider further surgery in order to reduce her risk of ovarian cancer. Because Myriad refused to accept Ms. Ceriani's insurance, however, her blood samples would not be processed unless she paid for the service out-of-pocket. Ms. Ceriani is unable to pay the full cost out-of-pocket and, to date, has not been tested and cannot determine her best medical course of action. Were Ms. Ceriani able to obtain genetic testing from Myriad, she would also want verification of the results of the *BRCA1/2* test before deciding whether to undergo removal of her ovaries. If the patents-in-suit were to be invalidated, Ms. Ceriani would pursue *BRCA1/2* genetic testing through laboratories other than Myriad, such as those of Drs. Chung and Ostrer. She would also seek verification of her *BRCA1/2* test results at a second lab. Ceriani Decl. ¶¶ 2-5, 7-11.

Plaintiff Runi Limary ("Ms. Limary") is a 32-year-old Asian-American woman who was diagnosed with aggressive breast cancer in November 2005. Following her diagnosis, she sought *BRCA1/2* genetic testing on the advice of her doctor. However, she was unable to be tested by Myriad until two years later, when she obtained insurance that provided coverage for the test. Her test results

informed her that she possessed a "genetic variant of uncertain significance" in her *BRCA1* gene frequently identified in women of Asian descent and other racial minorities but whose significance as an indicator of predisposition to cancer was unclear. However, her test did not examine all known types of mutations in her *BRCA* genes, including known large rearrangements. Ms. Limary seeks additional resources for testing and research that could reveal the significance of her genetic variant, including whether it is correlated with an increased risk of breast or ovarian cancer, and could allow her to make an informed decision about her future medical treatment. If the patents-in-suit were to be invalidated, Ms. Limary would immediately pursue additional *BRCA1/2* genetic testing through other laboratories, such as those of Drs. Chung and Ostrer. Such testing would include additional analysis to determine the significance of her *BRCA1* variant of unknown significance. Limary Decl. ¶¶ 2-6, 8-9.

Plaintiff Genae Girard ("Ms. Girard") is a 39-year-old woman who was diagnosed with breast cancer in 2006. Shortly after her diagnosis, she obtained *BRCA1/2* genetic testing from Myriad and tested positive for a deleterious mutation on the *BRCA2* gene. She sought, but

was unable to obtain a second opinion confirming the test result before making any decisions concerning prophylactic bilateral breast surgery and ovarian surgery. IF the patents-in-suit were to be invalidated, Ms. Girard would immediately pursue *BRCA1/2* genetic testing through other laboratories, such as those of Drs. Chung and Ostrer. Girard Decl. ¶¶ 2-5, 10.

Plaintiff Patrice Fortune ("Ms. Fortune") is a 48-year-old woman who was diagnosed with breast cancer in February 2009. Because Ms. Fortune has a family history of breast cancer, her genetic counselor and oncologist advised her to seek *BRCA1/2* genetic testing. However, as a result of incomplete coverage for Myriad's test by Ms. Fortune's health insurance, Ms. Fortune would be required by Myriad to pay the full out-of-pocket cost for her genetic testing. Because Ms. Fortune currently works in unpaid positions while receiving treatment for her cancer, she cannot afford the cost of Myriad's genetic testing. If the patents-in-suit were to be invalidated, Ms. Fortune would immediately seek testing through other laboratories, such as those of Drs. Chung and Ostrer, in addition to seeking a second opinion by another lab before making any major decisions about her treatment. Fortune Decl. ¶¶ 2-5, 8.

Plaintiff Vicky Thomason ("Ms. Thomason") is a 52-year-old woman who was diagnosed with ovarian cancer in 2006. She obtained *BRCA1/2* genetic testing from Myriad in 2007 at the advice of her doctor and genetic counselor and was found to be negative for mutations covered by that test. However, in light of her family history of cancer, her genetic counselor advised her that she was an appropriate candidate for the additional *BRCA1/2* genetic testing offered by Myriad that looks for large genetic rearrangements that are not detected by Myriad's standard genetic test. However, Ms. Thomason's insurance will not cover the entire cost of Myriad's additional test, and Ms. Thomason is unable to afford the extra cost. If the patents-in-suit were to be invalidated, Ms. Thomason would immediately seek *BRCA1/2* testing, including the large rearrangement testing that she currently cannot afford, through other laboratories, such as those of Drs. Chung and Ostrer. Thomason Decl. ¶¶ 2-6, 8, 10.

Plaintiff Kathleen Raker ("Ms. Raker") is a 42-year-old woman whose mother and maternal grandmother died from breast cancer. She obtained *BRCA1/2* genetic testing from Myriad in 2007 and was found to be negative for

mutations covered by that test. However, her genetic counselor advised her that she could still face hereditary risks for breast cancer due to a mutation in her *BRCA* genes that could not be detected by Myriad's standard test, but might be detected by Myriad's test for large rearrangements. Ms. Raker is unable to afford the cost of Myriad's additional testing and, to date, has not received this testing. Without those results, she cannot determine the risk of cancer she or her children face. If the patents-in-suit were to be invalidated, Ms. Raker would immediately pursue *BRCA1/2* testing through other laboratories, such as those of Drs. Chung and Ostrer. Raker Decl. ¶¶ 2-3, 5-7, 8-9, 11-12.

B. The Defendants

The USPTO is an agency of the Commerce Department of the United States. Compl. ¶ 27. The Plaintiffs assert only their claims for constitutional violations against the USPTO.

Myriad is a for-profit corporation located in Salt Lake City, Utah, doing business throughout the United

States. Myriad Genetics is a co-owner of one of the patents-in-suit and holds the exclusive licenses for the remaining ones. It is currently the sole clinical provider of full sequencing of the *BRCA* genes in the United States. Compl. ¶ 28.

The Directors are directors of the UURF, a not-for-profit corporation located in Salt Lake City, Utah, that the Plaintiffs allege is operated, supervised, and/or controlled by the University of Utah. The UURF is an owner or part-owner of all of the patents-in-suit.[4] Compl. ¶ 29.

C. ***BRCA1* and *BRCA2***

The human body is composed of cells. Contained in the nucleus of each cell are the genes that serve as the blueprints used by the body to create the proteins and gene products required for its function. Human genes are

[4] The United States of America, represented by the Secretary of Health and Human Services, is an additional owner of the '001, '441, '897, and '282 patents. Endo Recherche, Inc., of Quebec, Canada, HSC Research and Development Limited Partnership of Toronto, Canada, and the Trustees of the University of Pennsylvania are additional owners of the '492 and '857 patents. Compl. ¶ 30.

composed of unique combinations of four DNA[5] nucleotides (i.e., bases) referred to by the letters A, T, C, and G. The sequence of each gene reflects the string of hundreds or thousands of A, T, C, and G nucleotides that make up the gene. Each gene has a normal, or "wild-type" sequence of nucleotides. Compl. ¶¶ 33, 35, 36.

The sequence of any given human gene varies in nature from one person to another and frequently varies from the "wild-type" sequence. Some of the variations, referred to as "mutations" or "variants," can impact the body's ability to create proteins necessary for sound health. These mutations can include individual nucleotide substitutions (e.g., a T where G would normally appear in a gene), individual nucleotide deletions (e.g. a G being deleted altogether from a particular location in a gene), or much larger variations (e.g. a section of a gene containing numerous nucleotides is deleted or displaced). Mutations can be inherited from an individual's parents as well as be acquired during an individual's lifetime. Id.

[5] DNA, which stands for deoxyribonucleic acid, is a chemical compound made by the body. Compl. ¶ 34.

To find out if the nucleotide sequence of a person's gene differs from the normal, or "wild-type" nucleotide sequence for the gene, a genetic researcher or clinician can sequence the person's gene to determine its nucleotide sequence. Once the sequence of the gene has been obtained, the researcher or clinician can examine the entire sequence to see if the A, T, C, and Gs encode a healthy sequence, a sequence with mutations known to be associated with cancer, or a sequence with one or more variants of uncertain significance. Alternatively, the researcher or clinician can sequence and examine a small section of the gene where a particular mutation or variant is known to occur. The methods by which researchers or clinicians identify the sequence of either the whole gene or any part thereof are not patented in the claims at issue here and are well known in the field. Compl. ¶ 36.

In the 1990s, a number of genetic researchers around the world began looking for a human gene that correlated with an increased risk of breast and/or ovarian cancer. Many of those researchers, including the researchers who ultimately formed Myriad, were funded, at least in part, by the federal government. Researchers, using techniques widely available in the profession,

determined in 1990 that one gene that correlated with an increased risk of breast and/or ovarian cancer was located in the body on chromosome 17. Another research team that was eventually associated with Myriad, using techniques widely available in the profession, sequenced the precise gene, which was named *BRCA1* because of its correlation with breast cancer susceptibility. These researchers subsequently formed Myriad. Myriad sought, and ultimately obtained, several patents on this human *BRCA1* gene. Researchers also began looking for other genes similar to *BRCA1*, and Myriad, using techniques widely available in the profession, subsequently identified *BRCA2* and obtained a series of patents over the human *BRCA2* gene. As a result, Myriad holds, either through ownership or exclusive license, numerous patents relating to the human *BRCA1* and *BRCA2* genes. Compl. ¶¶ 41-45.

The patents for *BRCA1/2* were granted by the USPTO pursuant to a formal written policy that provides that naturally occurring genes can be patented if they are "isolated from their natural state and purified." Compl. ¶ 50. According to USPTO policy, an "isolated and purified" gene includes one that is simply removed from the body and separated from the other contents of the cell. Compl. ¶

51. However, the information dictated by the gene is identical whether it is inside or outside of the body, and an "isolated and purified" human gene performs the same function as the human gene in a person's body. Id. USPTO policy also permits patenting of comparisons or correlations created by nature, but identified by a patent holder. Compl. ¶ 53.

Everyone carries the *BRCA1* and *BRCA2* genes, but the sequence of each person's *BRCA* genes can differ. Compl. ¶ 37. Certain mutations in the genes are correlated with an increased risk of breast and/or ovarian cancer and may also be associated with other cancers, such as prostate and pancreatic cancers. Id. Women with these mutations have an approximately 40-85% lifetime risk of developing breast cancer. Compl. ¶ 39. Approximately 5-10% of women who develop breast cancer are likely to have a mutation in their *BRCA1* or *BRCA2* genes predisposing them to breast cancer and which they inherited from their parents. Compl. ¶ 38.

A *BRCA1/2* genetic test result that is positive for one of these mutations can have a substantial impact on a woman's medical decisions and health. Many women will

obtain earlier and more vigilant screening for breast and/or ovarian cancers, and some women may choose to have prophylactic surgery to remove their breasts and/or ovaries in order to reduce the risk of future cancers. Compl. ¶ 40.

D. Enforcement of the Patents-in-Suit

In the late 1990s, the GDL at the University of Pennsylvania was engaged in providing *BRCA1* genetic testing services to women. Kazazian Decl. ¶ 4. Around this time, Dr. Kazazian, one of the co-Directors of the GDL, met with Dr. Mark Skolnick ("Dr. Skolnick"), the Chief Science Officer at Myriad. During the meeting, Dr. Skolnick informed Dr. Kazazian that Myriad planned to stop the *BRCA1* and *BRCA2* testing being done by the GDL. Kazazian Decl. ¶ 6. Shortly thereafter, on or about May 29, 1998, Dr. Kazazian received a letter from William A. Hockett, Director of Corporate Communications for Myriad which asserted that Myriad is "the patent holder for the BRCA1 gene" covering, among other things "composition of matter covering the BRCA1 gene [and] any fragments of the BRCA1 gene." Ganguly Decl. ¶ 5. The letter further offered the

University a collaboration license of very limited scope. Id.

On or about August 26, 1998, Dr. Kazazian received a cease-and-desist letter from George A. Riley of O'Melveny & Myers, LLP, asserting that the Dr. Kazazian's commercial testing activities infringed the patents-in-suit and demanding that he cease "all infringing testing activity." Ganguly Decl. ¶ 6.

On or about June 10, 1999, the University of Pennsylvania general counsel, Robert Terrell, received a letter from Christopher Wright, Myriad's General Counsel, asserting that Dr. Kazazian's *BRCA* testing activities infringed the patents-in-suit and demanding that the university cease all such commercial genetic testing services. Ganguly Decl. ¶ 7. In a subsequent letter to the University dated September 22, 1999, Myriad reiterated its belief that the genetic testing activities being performed at the GDL infringed the patents-in-suit and repeated its demand that such activities cease. Ganguly Decl. ¶ 9.

As a result of these letters, the University of Pennsylvania advised Drs. Kazazian and Ganguly to discontinue their *BRCA1/2* testing, which they did. Kazazian Decl. ¶ 7; Ganguly Decl. ¶ 10.

During this same period, Dr. Harry Ostrer was sending patient samples to Dr. Kazazian for *BRCA1/2* related genetic screening. Ostrer Decl. ¶ 5. On May 21,1998, Dr. Ostrer also received a letter from William Hocket similar to that sent to Dr. Kazazian. The letter notified Dr. Ostrer of Myriad's patents and offered him a license for *BRCA*1/2-related genetic testing. Ostrer Decl. ¶ 7. Because of the narrow scope of the proposed license, Dr. Ostrer did not enter into a licensing agreement with Myriad. Id.

On or about September 15, 1998, Gregory Critchfield, the President of Myriad, sent a letter to Dr. Susan Nayfield of the National Cancer Institute ("NCI"). Ganguly Decl. Ex. 7. The letter assured Dr. Nayfield that Myriad would not interfere with research activities supported by the NCI in any way, but noted that Myriad had, over the past several months, sent several laboratories engaged in the "commercial testing" of the *BRCA1* gene draft

license agreements defining the conditions under which those laboratories would be allowed to conduct commercial genetic testing. Id.

On or about September 2, 1999, a Myriad representative sent a letter to a Georgetown laboratory demanding that it no longer sent genetic samples to the GDL for testing because such testing infringed the patents-in-suit. Ganguly Decl. ¶ 13. As a result of the letter, Georgetown stopped sending samples to the GDL for *BRCA1/2* screening. Id.

In December 2000, the director of the Yale DNA Diagnostics Laboratory (the "YDL") received a letter from Myriad directing that the YDL cease the *BRCA1/2* genetic testing that was being conducted in the laboratory because the testing allegedly infringed the patents-in-suit. Matloff Decl. ¶ 7. Following receipt of the letter, the laboratory ceased offering such genetic testing. Id.

In 2005, Ms. Matloff telephoned Myriad to inquire whether it was permissible for the YDL to perform genetic screening of the *BRCA* genes that looked for large rearrangement mutations. Matloff Decl. ¶ 8. Several

scientific studies had demonstrated that Myriad's full sequencing test missed large rearrangements that are also correlated with cancer risk. Myriad informed Ms. Matloff that this large rearrangement testing could not be done by the Yale laboratory because it would infringe the patents-in-suit. Id.

Myriad has also engaged in litigation to assert its rights under the patents-in-suit. In 1997 and 1998, Myriad filed suit against Oncormed, a company offering competing *BRCA1/2* genetic testing. See Myriad Genetics v. Oncormed, 2:97-cv-922 (D. Utah); Myriad Genetics v. Oncormed, 2:98-cv-35 (D. Utah). In November 1998, Myriad sued the University of Pennsylvania for infringing its *BRCA* patents. See Myriad Genetics v. Univ. of Pennsylvania, 2:98-cv-829 (D. Utah). Although the lawsuit was dismissed after the University agreed to cease its BRCA testing, the dismissal was "without prejudice." See 2:98-cv-829 (D. Utah) (docket entry 3).

As a result of these efforts, it is widely understood within the research community that Myriad has taken the position that any *BRCA1/2* related activity infringes its patents and that Myriad will assert its

patent rights against parties engaged in such activity. See, Ostrer Decl. ¶¶ 5-6; Chung Decl. ¶ 15; Hubbard Decl. ¶ 7; Kant Decl. ¶ 4; Matloff Decl. ¶¶ 7-9; Reich Decl. ¶ 5; see also Mildred K. Cho, et al., Effects of Patents and License on the Provision of Genetic Testing Services, 5 J. Molecular Diagnostics 3 (2003) (reporting that nine clinical genetic testing laboratories ceased *BRCA1/2* testing as a result of Myriad's patents).

III. THE PARTIES' CONTENTIONS

The Plaintiffs challenge the validity of claims 1, 2, 5, 6, 7, and 20 of patent 5,747,282 (the "'282 patent"); claims 1, 6, and 7 of patent 5,837,492 (the "'492 patent"); claim 1 of patent 5,693,473 (the "'473 patent"); claim 1 of patent 5,709,999 (the "'999 patent"); claim 1 of patent 5,710,001 (the "'001 patent"); claim 1 of patent 5,753,441 (the "'441 patent"); and claims 1 and 2 of patent 6,033,857 (the "'857 patent").

The Plaintiffs divide the claims-in-suit into four categories. The first category of claims, which include claims 1, 2, 5, and 6 of the '282 patent and claim 1 of the '492 patent, cover isolated, non-mutated forms of

BRCA1 and *BRCA2* as well as fragments of *BRCA1* of 15 nucleotides or more. The second category of claims, which includes claim 1 of the '473 patent, claim 7 of the '282 patent and claims 6 and 7 of the '492 patent, cover isolated forms of *BRCA1* and *BRCA2* that contain mutations that may or may not have any correlation with an increased risk of breast and ovarian cancer. The third category of claims, comprised of claim 1 of the '999 patent, covers any method of analyzing an individual's *BRCA1* gene to determine whether the individual's gene contains an inherited mutation. The fourth category of claims, which includes claim 1 of the '001 patent, claim 1 of the '441 patent, and claims 1 and 2 of the '857 patent, covers comparison of a patients' *BRCA1* and *BRCA2* gene sequences with the normal *BRCA1* and *BRCA2* gene sequences to determine whether there are differences that would indicate a genetic predisposition to breast cancer. Claim 20 of the '282 patent, which the Plaintiffs include in this fourth category of claims, covers a method of examining the growth of cells containing a mutated form of *BRCA1* following their treatment with a potential therapeutic compound. None of the claims in the fourth category of claims are limited to "isolated" DNA.

The Plaintiffs allege that because human genes are products of nature, laws of nature, and/or natural phenomena, and abstract ideas or basic human knowledge or thought, the claims-in-suit are invalid for violating Article 1, section 8, clause 8 of the United States Constitution, the First and Fourteenth Amendments to the Constitution, and 35 U.S.C. § 101 of the patent statute. Compl. ¶ 52, 54.

According to the Plaintiffs, these genes exist as naturally occurring products of nature, and Myriad did not invent, create, or in any way construct or engineer the genes. Rather, Myriad located them in nature and described their informational content as it exists and functions in nature. According to the Plaintiffs, Myriad did not invent, create, or in any way construct the differences that may be found when a patient's *BRCA1/2* gene sequences are compared to the normal *BRCA1/2* gene sequences or the correlations between certain mutations in *BRCA1/2* and an increased risk of breast and/or ovarian cancer. Compl. ¶¶ 46, 48.

Myriad currently offers two types of tests: the Comprehensive BRACAnalysis Test and the BRACAnalysis

Rearrangement Test ("BART"). The Comprehensive BRACAnalysis Test costs over $3000; BART costs approximately $600, although Myriad will offer BART testing for free to some women who meet certain criteria. Compl. ¶ 92, 94. Although Myriad's tests examine many mutations known to correlate with a predisposition to breast and/or ovarian cancer, they do not look for all mutations known to correlate with breast and/or ovarian cancer. Ledbetter Decl. ¶ 16. The Plaintiffs allege that Myriad's patents on *BRCA1/2* have allowed it to bar any other entity from conducting genetic testing on the *BRCA* genes despite the ability of other clinical laboratories, such as the laboratories of Drs. Chung, Ostrer, and Ledbetter, to do so and the desire of patients, such as Ms. Limary and Ms. Girard, to seek such alternative testing. Compl. ¶ 84. As a result, any person seeking testing of their *BRCA1/2* genes is required to utilize Myriad's tests. Compl. ¶ 90.

According to the Plaintiffs, Myriad also has the ability to prevent researchers from conducing any research examining the *BRCA* genes. Compl. ¶ 96. Myriad has permitted some scientists to conduct pure research on *BRCA1/2*, but the Plaintiffs allege that Myriad has no official policy permitting such research and has not

publicized its willingness to allow such research. Compl. ¶ 97. The Plaintiffs allege that the patents on the *BRCA* gene sequences deny researchers access to genomic information which, unlike other patented inventions, cannot be "invented around" or built upon to foster scientific progress. Commpl. ¶ 88. As a result, researchers are chilled from engaging in research on *BRCA1/2* as well as research on other genes that may interact with *BRCA1/2.* Compl. ¶ 98. Included in such activities would be the development of new tests for breast and/or ovarian cancer that might be linked to *BRCA1/2*. The Plaintiffs assert that this infringes on quality medical practice and compromises quality assurance and improvement of testing. Compl. ¶ 101; Ledbetter Decl. ¶ 23.

The Defendants have moved to dismiss the claims against them pursuant to Fed. R. Civ. P. 12(b)(1) on the grounds that the Court lacks subject matter jurisdiction over Plaintiffs' claims against the USPTO and that the Plaintiffs lack standing to bring this declaratory judgment action. The Defendants have also moved to dismiss the claims against the UURF Directors pursuant to Fed. R. Civ. P. 12(b)(2) on the grounds that the Court lacks personal jurisdiction over the Directors. Finally, the Defendants

move to dismiss the constitutional claims pursuant to Fed. R. Civ. P. 12(b)(6) for failure to sufficiently plead a claim.

IV. THERE IS SUBJECT MATTER JURISDICTION OVER THE CLAIMS AGAINST THE USPTO

The USPTO has moved to dismiss the Complaint, pursuant to Rule 12(b)(1), on the grounds that the Court lacks subject matter jurisdiction over the Plaintiffs' claims. A claim is "properly dismissed for lack of subject matter jurisdiction under Rule 12(b)(1) when the district court lacks the statutory or constitutional power to adjudicate it." Makarova v. United States, 201 F.3d 110, 113 (2d Cir. 2000). "When jurisdiction is challenged, the plaintiff 'bears the burden of showing by a preponderance of the evidence that subject matter jurisdiction exists.'" Arar v. Ashcroft, 532 F.3d 157, 168 (2d Cir. 2008) (quoting APWU v. Potter, 343 F.3d 619, 623 (2d Cir. 2003)). "[J]urisdiction must be shown affirmatively, and that showing is not made by drawing from the pleadings inferences favorable to the party asserting it." Shipping Fin. Servs. Corp. v. Drakos, 140 F.3d 129, 131 (2d Cir. 1998) (citation omitted). As such, the Court may rely on

evidence outside the pleadings, including declarations submitted in support of the motion and the records attached to these declarations. See Makarova, 201 F.3d at 113 ("In resolving a motion to dismiss . . . under Rule 12(b)(1), a district court . . . may refer to evidence outside the pleadings.").

The Plaintiffs premise their assertion of subject matter jurisdiction on 28 U.S.C. §§ 1331 & 1338(a).[6] 28 U.S.C. § 1331 vests the district courts with subject matter jurisdiction for "all civil actions arising under the Constitution." The USPTO, however, asserts that the Court lacks subject matter jurisdiction over Plaintiffs' claims against them in light of the "comprehensive scheme Congress established to govern patent grants."[7] Hitachi Metals, Ltd. v. Quigg, 776 F. Supp. 3, 7 (D.D.C. 1991). According to the USPTO, the existence of this comprehensive statutory

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[6] Although Plaintiffs also cite 28 U.S.C. § 2201 as a basis for jurisdiction, "[i]t is settled law that the Declaratory Judgment Act, 28 U.S.C. § 2201 (1994), does not enlarge the jurisdiction of the federal courts . . . and that a declaratory judgment action must therefore have an independent basis for subject matter jurisdiction." Concerned Citizens of Cohocton Valley, Inc. v. N.Y. State Dep't of Envtl. Conservation, 127 F.3d 201, 206 (2d Cir. 1997) (citing Skelly Oil Co. v. Phillips Petroleum Co., 339 U.S. 667, 671 (1950)).

[7] The USPTO also argues that sovereign immunity serves to bar this action. Courts, however, routinely entertain actions against federal agencies alleging violations of the Constitution. See, e.g., Reno v. ACLU, 521 U.S. 844 (1997). As Plaintiffs note in their Complaint, the only claims raised against the USPTO are of a constitutional nature. Compl. ¶ 27.

scheme reflects Congress' intention to preclude judicial challenges of the type brought by the Plaintiffs.

The cases cited by the USPTO, however, involved claims alleging statutory violations for which the Patent Act provided a remedy. The issue before the courts, then, was whether the existence of a comprehensive statutory scheme that addressed the alleged statutory violation precluded the right to also seek judicial review of the alleged violations. See Syntex (U.S.A.), Inc. v. U.S. Patent & Trademark Office, 883 F.2d 1570, 1572-74 (Fed. Cir. 1989) (concluding remedy provided by patent statute for alleged statutory violations precluded private judicial remedy for those claims);[8] Hallmark Cards, Inc. v. Lehman, 959 F. Supp. 539, 543 (D.D.C. 1997) (concluding Congress' statutory framework providing means to challenge issuance of Certificates of Correction "implicitly preclude[d]" a right to judicial relief); Hitachi Metals, 776 F. Supp. at 7-8 (finding statutory scheme for administrative and judicial review of patent reissue decisions precluded third-party judicial challenges to reissue process).

[8] The Syntex opinion noted in passing that the plaintiff had pled a violation of the 5th Amendment, but included no discussion concerning the claim in its analysis of subject matter jurisdiction.

In Bush v. Lucas, 462 U.S. 367 (1983), cited by the USPTO, the Supreme Court considered whether an employee subjected to adverse employment action as a result of his criticism of the federal agency employing him could maintain a suit against the agency for violation of his First Amendment rights. Id. at 369-72. Noting that "the ultimate question on the merits . . . may appropriately be characterized as one of 'federal personnel policy,'" id. at 380-81, the Court went on to describe Congress' "repeated consideration of the conflicting interests involved in providing job security, protecting the right to speak freely, and maintaining discipline and efficiency in the federal workforce." Id. at 385. The result, the Court concluded, was an "elaborate, comprehensive scheme" within which "Constitutional challenges to agency action, such as First Amendment claims raised by petitioner, are fully cognizable." Id. As a result, the Court was presented with a question "quite different from the typical remedial issue confronted by a common-law court" since the issue was not whether a judicial remedy should be created where none existed, but rather whether a judicial remedy should be created where a plaintiff was merely dissatisfied by the statutory remedy Congress provided for his alleged wrong. Id. at 388.

While the USPTO notes the existence of a comprehensive scheme to redress violations of the Patent Act, it cites to no comparable statutory scheme providing a remedy for persons who complain about the constitutionality of patents issued by the USPTO and/or the policies and practices of the USPTO. See Block v. Cmty. Nutrition Inst., 467 U.S. 340, 349 (1984) ("[W]hen a statute provides a detailed mechanism for judicial consideration of particular issues at the behest of particular persons, judicial review of those issues at the behest of other persons may be found to be impliedly precluded." (emphasis added)); see generally Marbury v. Madison, 5 U.S. 137 (1803). In such circumstances, the Supreme Court has held that Congress did not intend to preclude enforcement of federal rights through private actions. See Wright v. Roanoke, 479 U.S. 418, 427-28 (1987) (citing absence of statutorily defined private judicial remedy for alleged violation of federal housing law as evidence that Congress did not intend to foreclose private right of action). Indeed, even when Congress has created a statutory remedy, if that remedy is not coextensive with the remedy provided by the Constitution, plaintiffs may still bring a separate action to enforce the Constitution. See Fitzgerald v.

Barnstable Sch. Comm., __ U.S. __ , 129 S. Ct. 788, 796-97 (2009).

The novel circumstances presented by this action against the USPTO, the absence of any remedy provided in the Patent Act, and the important constitutional rights the Plaintiffs seek to vindicate establish subject matter jurisdiction over the Plaintiffs' claim against the USPTO.[9] See, e.g., Reno v. ACLU, 521 U.S. 844 (1997); Mace v. Skinner, 34 F.3d 854, 859-60 (9th Cir. 1994).

V. THERE IS STANDING

A. The Plaintiffs Have Standing to Sue the USPTO for Constitutional Violations

The "judicial power . . defined by Art. III is not an unconditioned authority to determine the constitutionality of legislative or executive acts" but, rather, is limited to the resolution of "cases" and

[9] Although the USPTO suggests that finding subject matter jurisdiction over Plaintiffs' constitutional claims would open the gates to a flood of challenges to patents based on alleged constitutional violations, it is difficult to see how a colorable claim for constitutional violations could arise out of patents for more commonly patented inventions, such as computer chips or carburetors.

"controversies." Valley Forge Christian Coll. v. Ams. United for Separation of Church & State, Inc., 454 U.S. 464, 471 (1982); Lujan v. Defenders of Wildlife, 504 U.S. 555, 559-60 (1992). An "essential and unchanging part" of that limitation is the doctrine of standing. Lujan, 504 U.S. at 560. Indeed, "[t]he Art. III doctrine that requires a litigant to have 'standing' to invoke the power of a federal court is perhaps the most important of these doctrines." Allen v. Wright, 468 U.S. 737, 750 (1984). "At an irreducible minimum, Art. III requires the party who invokes the court's authority to show (1) that he personally has suffered some actual or threatened injury as a result of the putatively illegal conduct of the defendant, that (2) the injury fairly can be traced to the challenged action, and (3) is likely to be redressed by a favorable decision." Valley Forge, 454 U.S. at 472 (internal citations omitted).[10]

Beyond these constitutional requirements, a plaintiff must also satisfy certain prudential standing

[10] The USPTO's challenge to Plaintiffs' standing is intertwined with its challenge to Plaintiffs' subject matter jurisdiction. See Syntex, 882 F.2d at 1573 ("The standing and reviewability inquiries tend to merge. A plaintiff cannot claim standing based on violation of an asserted personal statutorily-created procedural right when Congress intended to grant that plaintiff no such right." (quoting Banzhaf v. Smith, 737 F.2d 1167, 1170 n.* (D.C. Cir. 1984))).

requirements, based on the principle that the judiciary should "avoid deciding questions of broad social import where no individual rights would be vindicated." Phillips Petroleum Co. v. Shutts, 472 U.S. 797, 804 (1985). Prudential standing requires, inter alia, that a party "assert his own legal interests rather than those of third parties," id. at 804, and that a claim must not be a "generalized grievance" shared in by all or a large class of citizens, Warth v. Seldin, 422 U.S. 490, 499 (1975). Prudential standing also addresses whether "the constitutional or statutory provision on which [a plaintiff's] claim rests properly can be understood as granting persons in the plaintiff's position a right to judicial relief." See id. at 499-500. Thus, the litigant's complaint must fall within the "zone of interests to be protected or regulated by the statute or constitutional guarantee in question." Valley Forge, 454 U.S. at 475.

The Defendants allege that it is well established that third parties do not have standing to challenge the USPTO's issuance of a patent. The authorities cited by the USPTO, however, address a party's standing to bring claims for statutory violations and establish only that the

existence of a comprehensive framework within the Patent Act designed to address certain statutory violations may demonstrate Congressional intent to foreclose a judicial remedy for those violations. See Syntex, 882 F.2d at 1572-74; Hitachi Metals, 776 F. Supp. at 7-8; Godtfredsen v. Banner, 503 F. Supp. 642, 644-45 (D.D.C. 1980) (finding statutory remedies for claims of examiner error during interference proceedings precluded judicial review of the proceedings prior to the exhaustion of administrative remedies).[11] As discussed supra in Section IV, these cases do not, as the USPTO suggests, establish that the remedial scheme provided by the Patent Act for statutory violations divests the Plaintiffs of standing to assert constitutional claims for which the Patent Act provides no remedy.

The USPTO also argues that the Plaintiffs do not have standing because the injuries alleged are not "fairly

[11] Animal Legal Defense Fund, 932 F.2d 920 (Fed. Cir. 1991), cited by the USPTO, did not involve allegations of constitutional violations. Moreover, the court's analysis of standing turned on the specific APA provisions involved and was, in substance, a finding that no legally cognizable right was violated. See id. at 929-30. The court's holding also turned on the fact that no patents on animals had been granted and therefore any harm that might occur in the future from such patents was speculative. Id. at 933. The same cannot be said here, where patents over *BRCA1/2* have already been granted and have been used to prevent Plaintiffs from engaging in clinical analysis of the *BRCA1/2* genes, from informing women about testing options other than by Myriad, and from obtaining genetic testing or second opinions. Plaintiffs alleged harms are therefore not the type of speculative harms at issue in Animal Legal Defense Fund.

traceable" to the USPTO's allegedly improper conduct. The "fairly traceable" requirement "examines the causal connection between the assertedly unlawful conduct and the alleged injury." Allen, 468 U.S. at 753 n.19. While the USPTO is correct that Myriad's refusal to license its patent broadly contributes to Plaintiffs' alleged injuries, the patents were issued by the USPTO, in accordance with its policies and practices. It is those policies and practices that the Plaintiffs allege are unconstitutional. The injury alleged is therefore "fairly traceable" to the USPTO.

Finally, the USPTO argues that Plaintiffs' claim against it fails to meet the redressibility requirement, which "examines the causal connection between the alleged injury and the judicial relief requested." Allen, 468 U.S. at 753 n.9. The Plaintiffs ask the Court to enjoin the Defendants from taking any actions to enforce the challenged claims in Myriad's patents. Fairly included in this prayer for relief is a request that the Court declare unconstitutional the USPTO's policies and practices with respect to the challenged claims and similar classes of claims. Granting Plaintiffs' request for relief would serve to render the claims-at-issue definitionally invalid.

As a result, the Plaintiffs would be allowed to engage in conduct currently prohibited by Myriad's patents, and the alleged injuries would be redressed.

B. The Plaintiffs Have Established Standing to Sue Myriad and the Directors

Article III limits federal jurisdiction to disputes involving an actual "case or controversy," and not merely "a difference or dispute of a hypothetical or abstract character." Aetna Life Ins. Co. v. Haworth, 300 U.S. 227, 240 (1937). As the Supreme Court has recently observed, there exists no bright-line rule for determining whether an action satisfies the case or controversy requirement. MedImmune, Inc. v. Genentech, Inc., 549 U.S. 118, 127 (2007). Rather, "[t]he difference between an abstract question and a 'controversy' contemplated by the Declaratory Judgment Act is necessarily one of degree, and it would be difficult, if it would be possible, to fashion a precise test for determining in every case whether there is such a controversy." Md. Cas. Co. v. Pac. Coal & Oil Co., 312 U.S. 270, 273 (1941). Consequently, "the analysis must be calibrated to the particular facts of each case."

Cat Tech LLC v. TubMasters, Inc., 528 F.3d 871, 879 (Fed. Cir. 2008).

"Whether an actual case or controversy exists so that a district court may entertain an action for a declaratory judgment of non-infringement and/or invalidity is governed by Federal Circuit law." MedImmune, Inc. v. Centocor, Inc., 409 F.3d 1376, 1378 (Fed. Cir. 2005) (citations omitted), rev'd on other grounds, 549 U.S. 118 (2007). "The purpose of the Declaratory Judgment Act . . . in patent cases is to provide the allegedly infringing party relief from uncertainty and delay regarding its legal rights." Goodyear Tire & Rubber Co. v. Releasomers, Inc., 824 F.2d 953, 956 (Fed. Cir. 1987). As the Federal Circuit has explained:

> [A] patent owner . . . attempts extra-judicial enforcement with scare-the-customer-and-run tactics that infect the competitive environment of the business community with uncertainty and insecurity . . . . Before the Act, competitors . . . were rendered helpless and immobile so long as the patent owner refused to grasp the nettle and sue. After the Act, those competitors were no longer restricted to an in terrorem choice between the incurrence of a growing potential liability for patent infringement and abandonment of their enterprises; they could clear the air by suing for a judgment that would settle the conflict of interests.

Elecs. for Imaging, Inc. v. Coyle, 394 F.3d 1341, 1346 (Fed. Cir. 2005) (quoting Arrowhead Indus. Water, Inc. v. Ecolochem, Inc., 846 F.2d 731, 735 (Fed. Cir. 1988), overruled on other grounds by MedImmune, 549 U.S. 118).

The Federal Circuit's jurisprudence governing a party's standing to seek a declaratory judgment of patent invalidity was recently revised by the Supreme Court in MedImmune, 549 U.S. 118. There, the Supreme Court considered whether the licensee of a patent had standing to seek a judgment declaring the underlying patent invalid, unenforceable, or not infringed without first breaching or terminating the license agreement. Id. at 137. In concluding that subject matter jurisdiction existed over the plaintiff's declaratory judgment claim, the Supreme Court rejected the Federal Circuit's "reasonable apprehension of suit" test as conflicting with the Court's precedent. Id. at 132 n.11; see also Revolution Eyewear, Inc. v. Aspex Eyewear, Inc., 556 F.3d 1294, 1297 (Fed Cir. 2009) (observing that "the Federal Circuit's requirements, specific to patent cases, that there be both a threat or other action by the patentee sufficient to create a reasonable apprehension of infringement suit, and present activity that could constitute infringement or concrete

steps taken with the intent to conduct such activity, were more rigorous than warranted by the principle and purpose of declaratory actions.").[12] Instead, the Court held that the jurisdictional analysis was properly based on an examination of "all the circumstances." MedImmune, 549 U.S. at 127.

Under the "all the circumstances" test, "the question in each case is whether the facts alleged, under all the circumstances, show that there is a substantial controversy, between the parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment." Id. at 127 (quoting Md. Cas. Co., 312 U.S. at 273). This "more lenient legal standard facilitates or enhances the availability of declaratory judgment jurisdiction in patent cases," and, accordingly, there is now an "ease of achieving declaratory judgment jurisdiction." Micron Tech. v. Mosaid Techs. Inc., 518 F.3d 897, 902 (Fed. Cir. 2008). Courts in this district have likewise recognized that since

[12] Under the "reasonable apprehension of suit" test, determining whether a party seeking a declaratory judgment of invalidity possessed the necessary standing required examining (1) "whether the declaratory judgment plaintiff actually produced or was prepared to produce an infringing product;" and (2) "whether conduct by the patentee had created on the part of the declaratory judgment plaintiff a reasonable apprehension that the patentee would file suit if the allegedly infringing activity continued." Sony Elecs. Inc v. Guardian Media Techs., Ltd., 497 F.3d 1271, 1283 (Fed. Cir. 2007).

MedImmune, "the trend is to find an actual controversy, at least where the declaratory judgment plaintiff's product arguably practices a patent and the patentee has given some indication it will enforce its rights." Diamonds.net LLC v. IDEX Online, Ltd., 590 F. Supp. 2d 593, 597-98 (S.D.N.Y. 2008).

Although MedImmune did not define the precise contours of the "all the circumstances" test, guidance is provided by other courts' standing analysis. First, there must be some affirmative act by the defendant relating to enforcement of its patent rights. See, e.g., Prasco, LLC v. Medicis Pharm. Corp., 537 F.3d 1329, 1338-39 (Fed. Cir. 2008); SanDisk Corp. v. STMicroelectronics, Inc., 480 F.3d 1372, 1380-81 (Fed. Cir. 2007) ("[J]urisdiction generally will not arise merely on the basis that a party learns of the existence of a patent owned by another or even perceives such a patent to pose a risk of infringement, without some affirmative act by the patentee."). Second, the declaratory judgment plaintiff must have undertaken "meaningful preparation to conduct potentially infringing activity." Cat Tech LLC, 528 F.3d at 880. This inquiry ensures that a party does not seek a declaratory judgment "merely because it would like an advisory opinion on

whether it would be liable for patent infringement if it were to initiate some merely contemplated activity." Arrowhead, 846 F.2d at 736 (citations omitted). Whether there exists "sufficient 'preparation' is a question of degree to be resolved on a case-by-case basis." Id. (citing Md. Cas. Co., 312 U.S. at 273).

1. Affirmative Acts by the Defendants

The Defendants assert that in order to satisfy the "affirmative act" requirement for declaratory judgment standing, there must be some act by the Defendants directed towards the Plaintiffs. As an initial matter, the Defendants have, in fact, taken specific affirmative acts toward Drs. Kazazian and Ganguly.[13] Moreover, other courts have recognized that "an overt, specific act toward the declaratory judgment plaintiff is not required to demonstrate the existence of an actual controversy." Edmunds Holding Co. v. Autobytel, Inc., 598 F. Supp. 2d 606, 610 (D. Del. 2009).

[13] The Defendants argue that the cease-and-desist letters addressed to the University of Pennsylvania cannot be viewed as affirmative acts directed towards Dr. Ganguly. However, the letters were designed to stop the *BRCA1/2* testing being conducted by the lab jointly overseen by Drs. Kazazian and Ganguly, and Defendants seek to draw an overly formalistic distinction.

The cases cited by the Defendants unquestionably considered the absence of "affirmative acts" directed towards the plaintiff in finding a lack of standing to bring the declaratory judgment action. None of the cases, however, establish a requirement that only acts directed towards the plaintiff could be considered for purposes of the standing analysis or even that there must exist acts specifically directed towards the plaintiffs in order to establish standing. Instead, in most of the cases, the dismissal was based on a lack of any legally cognizable acts by the defendant upon which a declaratory judgment could be established. See, e.g., Prasco, 537 F.3d at 1334, 1340 (observing that the plaintiff's only basis for standing was the plaintiff's allegation that its product did not infringe the defendants' patents); Indigodental GMBH & Co. KG v. Ivoclar Vivadent, Inc., No. 08 Civ. 7657 (RJS), 2008 WL 5262694, at *2 (S.D.N.Y. Dec. 10, 2008) (concluding that "Plaintiff had done little more than become aware of Defendant's patent"); Document Sec. Sys., Inc. v. Adler Techs., Inc., No. 03-CV-6044, 2008 WL 596879, at *10-*11 (W.D.N.Y. Feb. 29. 2008) (finding single page of deposition testimony and an unrelated patent litigation insufficient basis for standing); Broadcom Corp. v. Qualcomm Inc., No. 08cv1829 WQH (LSP), 2009 WL 684835, at

*6 (S.D. Cal. Mar. 12, 2009) (citing, as the basis for its holding, plaintiff's failure "to specify any affirmative act by the defendants" that would support jurisdiction); Impax Labs., Inc v. Medicis Pharm. Corp., No. C-08-0253 MMC, 2008 WL 1767044, at *2 (N.D. Cal. Apr. 16, 2008) (finding plaintiff's filing of an Abbreviated New Drug Application coupled with defendant's public statements of intent to enforce patents insufficient to create an "actual controversy"); The Wooster Brush Co. v. Bercom Int'l, LLC, No. 5:06CV474, 2008 WL 1744782, at *4-*5 (N.D. Ohio Apr. 11, 2008) (finding defendant had never engaged in any activity that would suggest the plaintiffs infringed its patent); Baker Hughes Oilfield Operations, Inc. v. Reedhycalog UK, Ltd., No. 2:05-CV-931, 2008 WL 345849, at *2-*3 (D. Utah Feb. 6, 2008) (dismissing case where letters from defendant did not indicate that it thought plaintiffs were infringing its patents).[14]

[14] In Geospan Corp. v. Pictometry Int'l Corp., 598 F. Supp. 2d 968 (D. Minn. 2008), the court observed that the only instances post-MedImmune in which declaratory judgment jurisdiction had been found to exist were those in which the defendants had engaged in some form of activity against the plaintiff. Id. at 970. It did not, however, state a general rule that actions directed towards the plaintiff were required to establish subject matter jurisdiction over a declaratory judgment action, nor how such a requirement would be consistent with the "all the circumstances" test. To the extent that Geospan may be read to set forth such a requirement concerning a defendant's relevant "affirmative acts," the Court declines to adopt a similar holding.

A requirement that there be a specific, affirmative act directed towards the plaintiff to establish standing to seek a declaratory judgment of patent invalidity would be inconsistent with the Supreme Court's mandate that the Court examine "the facts alleged, under all the circumstances," in assessing the existence of a case or controversy. See MedImmune, 549 U.S. at 127 (quoting Md. Cas. Co., 312 U.S. at 273). As the Federal Circuit has previously stated:

> Article III jurisdiction may be met where the patentee takes a position that puts the declaratory judgment plaintiff in the position of either pursuing arguably illegal behavior or abandoning that which he claims a right to do. We need not define the outer boundaries of declaratory judgment jurisdiction, which will depend on the application of the principle of declaratory judgment jurisdiction to the facts and circumstances of each case.

SanDisk, 480 F.3d at 1381. In light of these principles, an examination of the totality of Myriad's conduct relating to the patents-in-suit is appropriate.

The Defendants raise several challenges to the legal significance of the acts relied on by the Plaintiffs to establish standing. First, the Defendants argue that Myriad's 1998 letter to Dr. Kazazian is too old to serve as

the basis for a case or controversy. The Federal Circuit cases cited by the Defendants in support of their argument, however, pre-date MedImmune and examined the timeliness of letters in the context of the now-defunct "apprehension of suit" test. See Sierra Applied Scis., Inc. v. Advanced Energy Indus., Inc., 363 F.3d 1361, 1374 (Fed. Cir. 2004); Cygnus Therapeutics Sys. v. ALZA Corp., 92 F.3d 1153, 1159 (Fed. Cir. 1996). Given the recent changes to the standing analysis for declaratory judgment claims, those cases no longer serve as controlling authorities. See Benitec Austl., Ltd. v. Nucleonics, Inc., 495 F.3d 1340, 1346 (Fed. Cir. 2007) (questioning holdings in prior cases applying the "reasonable apprehension of suit" test for declaratory judgment jurisdiction in light of MedImmune). Furthermore, the Defendants cite no authority that would preclude the Court from considering the letter as part of "all the circumstances."

While the district court cases cited by the Defendants correctly applied the "all the circumstances" test in dismissing the declaratory judgment actions, they are also distinguishable from the present situation. In Avante, the affirmative act cited by the plaintiff consisted of a single, brief infringement suit lasting a

few weeks. See Avante Int'l Tech., Inc. v. Hart Intercivic, Inc., No 08-832-GPM, 2009 WL 2431993, at *3 (S.D. Ill. July 31, 2009). In Edmunds Holding, the court's dismissal turned on the a finding that "[n]one of the facts adduced by [the plaintiff] established that [the defendant] believe[d] [the plaintiff] to be infringing the '517 patent." Edmunds Holding, 598 F. Supp. 2d at 610. While the Court agrees that an 11-year old letter may not, alone, be sufficient to establish declaratory judgment jurisdiction, those are not the circumstances presented here. Myriad's assertions of its patent rights consist not only of the letter to Dr. Kazazian, but a continuing course of conduct over a period of several years. In addition, Defendants' prior efforts to prevent the Plaintiffs and other similarly situated parties from engaging in *BRCA1/2* testing establish that Plaintiffs' planned activities would be considered infringing by the Defendants. The totality of the circumstances, as alleged by the Plaintiffs, cannot be said to be comparable to the circumstances presented by Avante and Edmunds.

The Defendants also dispute the relevance of prior litigation to the standing analysis. The Defendants argue at the outset that only litigation brought against

the Plaintiffs may be considered by the Court in its jurisdictional analysis; none of the cited cases, however, supports such a rule,[15] and, as discussed supra, this approach is inconsistent with the premise of the "all the circumstances" test. Further, although the lawsuits brought by Myriad against Oncormed and the University of Pennsylvania were dismissed, both serve as evidence of Myriad's willingness to assert its rights granted by the patents-in-suit against others. See Prasco, 537 F.3d at 1341 ("Prior litigious conduct is one circumstance to be considered in assessing whether the totality of the circumstances creates an actual controversy."). Finally, the suit against the University of Pennsylvania was dismissed without prejudice and therefore would not bar a new infringement action by Myriad against the University of Pennsylvania or Drs. Kazazian and Ganguly. Consequently, Myriad's prior litigations involving the patents-in-suit are fairly included in the Court's standing analysis.

[15] Prasco held only that the particular prior lawsuit in question did not establish the existence of a case or controversy between the parties in light of the absence of any other evidence that the defendants had taken a position adverse to the plaintiff's position. See Prasco, 537 F.3d at 1340, 1341 n.9. It did not set forth a general rule concerning the consideration of prior litigation. The court in Edmunds similarly did not prohibit consideration of prior litigation directed to third parties. See Edmunds, 598 F. Supp. 2d at 610 (distinguishing cases cited by the plaintiff in support of its assertion of the existence of case or controversy).

The Plaintiffs cite counsel's August 11, 2009 letter to Defendants' counsel requesting a waiver of claims against intended *BRCA*-related activities and Defendants' subsequent refusal to grant such a waiver as evidence in support of the existence of subject matter jurisdiction. See Ravicher Decl. Ex. 1. However, the presence or absence of jurisdiction must be determined on the facts existing at the time the complaint under consideration was filed. GAF Bldg Materials Corp. v. Elk Corp. of Dallas, 90 F.3d 479, 483 (Fed. Cir. 1996) (citing Arrowhead, 846 F.2d at 734 n.2). Because the filing of the Complaint pre-dated the August 11, 2009 letter, the letter does not factor into the standing analysis.

Taken together, Plaintiffs' allegations establish the existence of sufficient "affirmative acts" by the Defendants for purposes of declaratory judgment jurisdiction. The Defendants have asserted their right to preclude others from engaging in *BRCA1/2* genetic testing through personal communications, cease-and-desist letters, licensing offers, and litigation. The result, as alleged by the Plaintiffs and supported by affidavits, is the widespread understanding that one may engage in *BRCA1/2* testing at the risk of being sued for infringement

liability by Myriad. This places the Plaintiffs in precisely the situation that the Declaratory Judgment Act was designed to address: the Plaintiffs have the ability and desire to engage in *BRCA1/2* testing as well as the belief that such testing is within their rights, but cannot do so without risking infringement liability.[16]

In light of "all the circumstances," there exists a sufficiently "real and immediate injury or threat of future injury that is caused by the defendants" to satisfy the "affirmative act" requirement for a declaratory judgment action. Prasco, 537 F.3d at 1339; see also Adenta GmbH v. OrthoArm, Inc., 501 F.3d 1364, 1370 (Fed. Cir. 2007); Micron Tech., 518 F.3d at 899 (patentee "pursues a systematic licensing and litigation strategy").

2. Meaningful Preparations for Infringing Action

The Defendants also assert that the Plaintiffs have failed to demonstrate the existence of "meaningful preparation" to engage in infringing activity.

[16] Indeed, in light of the widespread knowledge of Myriad's *BRCA1/2* patents and the breadth of the relevant claims, a finding of patent infringement would likely be considered willful and result in treble damages. See 35 U.S.C. § 284.

With respect to the researcher Plaintiffs, the Defendants argue that the Plaintiffs allege only that they are "ready, willing, and able" to infringe and that such expressions of desire and ability are insufficient to establish "meaningful preparations" without reference to specific preparatory activities. However, the "meaningful preparation" inquiry properly focuses on whether the Plaintiffs are meaningfully prepared to engage in the infringing act such that the court's decision would serve as more than an "advisory opinion." See Cat Tech LLC, 528 F.3d at 879; SanDisk, 480 F.3d at 1381 ("[A] party need not risk a suit for infringement by engaging in the identified activity before seeking a declaration of its legal rights."). Where plaintiffs' normal course of business renders them meaningfully prepared to engage in the infringing activity at issue, the lack of some identifiable preparatory effort separate and apart from their normal activities cannot, without more, serve as the basis for finding that there has been no "meaningful preparation" for purposes of declaratory judgment jurisdiction. To hold otherwise would render those most prepared to engage in infringing activity, i.e., those for whom essentially no additional preparation is required to perform the infringing activity, the parties least likely to satisfy

the standing requirements for a declaratory judgment action.

The Defendants also cite Benitec, 495 F.3d 1340, and Mega Lift Sys., LLC v. MGM Well Services, Inc., No. 6:08 CV 420, 2009 WL 1851919 (E.D. Tex. June 29, 2009), in support of their assertion that the researcher Plaintiffs' preparation is insufficient as a matter of law to establish standing. In Benitec, the Federal Circuit found the plaintiff's plans to adapt its human gene silencing technology for use in the animal husbandry and veterinary markets insufficiently immediate for standing purposes. Benitec, 495 F.3d at 1349. The court based its holding on the fact that (1) the plaintiff had merely stated that it "expect[ed]" to begin work "shortly" on adapting its existing gene silencing technology to livestock; (2) the plaintiff had provided insufficient information for the court to assess whether the plaintiff's planned activities would be infringing; and (3) the parties agreed that the plaintiff's planned activities would fall within the safe harbor provision to infringement under 35 U.S.C. § 271(e)(1). See Benitec, 495 F.3d at 1349. In Mega Lift, the district court relied on the fact that the plaintiff had failed to include in its complaint any "allegation

about its readiness to manufacture and sell" the future product that was the subject of the declaratory judgment action. Mega Lift, 2009 WL 1851919, at *4.

The factual circumstances, as set forth in the Plaintiffs' affidavits, render Benitec and Mega Lift distinguishable on their facts and demonstrate sufficient preparation by the researcher Plaintiffs to establish standing. The Plaintiffs have demonstrated that the researcher Plaintiffs are poised to begin *BRCA1/2* testing and that the patents-in-suit present the only obstruction to doing so.[17] See, e.g., Chung Decl. ¶¶ 13, 15-18; Ledbetter Decl. ¶¶ 8-9. All are established human geneticists whose laboratories are routinely engaged in genetic testing and therefore possess the necessary equipment and expertise to immediately begin performing *BRCA1/2* genetic testing. Compl. ¶¶ 11-16; Kazazian Decl. ¶¶ 3-5, 8-11; Ganguly Decl. ¶¶ 3, 14; Chung Decl. ¶¶ 17-18, 21; Ostrer Decl. ¶¶ 8-10, 13; Ledbetter Decl. ¶¶ 18-19 (speaking for himself and Dr. Warren). Moreover, Drs. Kazazian, Ganguly, and Ostrer had previously engaged in

[17] The affidavits also establish that the proposed *BRCA* testing would infringe the claims-in-suit and provide sufficient information to satisfy the Federal Circuit's requirement that "the existence of a case or controversy [] be evaluated on a claim-by-claim basis." Jervis B. Webb Co. v. Southern Sys., Inc., 742 F.2d 1388, 1399 (Fed. Cir. 1984).

BRCA1/2 testing prior to Myriad's assertion of its patent rights against them.[18] Kazazian Decl. ¶¶ 4-10; Ganguly Decl. ¶¶ 3-10. Consequently, the researcher Plaintiffs are meaningfully prepared to begin "BRCA testing to advance research and/or to offer . . . an important service to the public" and "could do so within a matter of weeks." Ganguly Decl. ¶ 14; see also Ledbetter Decl. ¶ 18.[19]

Plaintiffs' affidavits similarly establish that members of the various medical organizations, represented by the organizations under the "doctrine of associational standing," are, like the researcher Plaintiffs, also meaningfully prepared and possess the desire to engage in *BRCA1/2* testing were the patents-in-suit invalidated. See, e.g., Hegde Decl. ¶ 6-12; Hubbard Decl. ¶ 3-9; Kant Decl. ¶ 4-6.

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[18] Defendants argue that Drs. Kazazian and Ganguly state only that they would "consider" engaging in infringing Myriad's patents, and that such speculative intent cannot satisfy the "meaningful preparation" prong. However, the proper focus of this inquiry is whether the plaintiffs are meaningfully prepared, not whether they have made a final, conclusive decision to engage in the infringing activity. See Cat Tech LLC, 528 F.3d at 879 (describing inquiry as requiring "a showing of 'meaningful preparation' for making or using that product").

[19] According to Plaintiffs' counsel, all that would be required to begin genetic testing would be to order the necessary oligonucleotides specific to the *BRCA1/2* genes, a delay of less than a month. Although Defendants raise the possibility that state certification may, in some instances, be required in order for Plaintiffs to engage in clinical *BRCA* testing, they have offered no evidence suggesting that this would constitute a delay of sufficient length to render the dispute of insufficient immediacy to warrant judicial intervention.

The remaining non-researcher Plaintiffs have also established the existence of sufficient "meaningful preparations" to satisfy this prong of the standing inquiry. As an initial matter, the non-researcher Plaintiffs cannot be found to have failed to satisfy the meaningful preparation requirement on the grounds that the researcher Plaintiffs have not yet chosen to engage in infringing *BRCA* testing. Potential contributory infringers, such as the non-researcher Plaintiffs, may very well understand the precise nature of, and be prepared to take advantage of, the services of a potential infringer were the latter not prevented from offering those services by a third party's assertion of its patent rights. Here, it is alleged that the researcher Plaintiffs would offer infringing *BRCA1/2* genetic testing services of the type the non-researcher Plaintiffs would solicit or encourage others to solicit. The Defendants cite no authorities establishing that only potential direct, and not potential contributory infringers can have standing in a declaratory judgment action.[20]

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[20] Animal Legal Defense Fund, cited by Defendants, addressed the standing of a third party to challenge the findings of a PTO Examiner during examination of a patent and has no bearing on standing in the context of a declaratory judgment action. See Animal Legal Defense Fund, 932 F.2d, 920, 930 (Fed. Cir. 1991) ("A third party has no right to intervene in the prosecution of a particular patent application to prevent issuance of an allegedly invalid patent.").

The Plaintiffs have set forth sufficient factual allegations to establish that the non-researcher Plaintiffs are meaningfully prepared to engage in contributory infringement so as to render the controversy between them and the Defendants of "sufficient immediacy and reality." MedImmune, 549 U.S. at 126 (citation omitted); see, e.g., Matloff Decl. ¶¶ 4, 10-15; Reich Decl. ¶¶ 3, 7-11, 14-15; Brenner Decl. ¶¶ 2-3, 9; Ceriani Decl. ¶ 11; Limary Decl. ¶ 9; Girard Decl. ¶ 10; Fortune Decl. ¶ 8; Thomason Decl. ¶ 10. Indeed, for these Plaintiffs, whose infringing activity would constitute nothing more than taking advantage of alternatives to Myriad's *BRCA1/2* testing or encouraging others to do the same, it is difficult to conceive what more "meaningful preparation" would be required.[21]

The contentions of the Defendants in urging the Plaintiffs' lack of standing to bring a declaratory judgment action present a stark alternative: the deliberate violation of the patents-in-suit in order to challenge their constitutionality and validity. The risks, expense,

[21] Similarly, it is difficult to envision what preparatory activity would be required to infringe the claims-in-suit covering the comparison of *BRCA1/2* gene sequences.

and uncertainty of that protracted litigation process to compel the Defendants to defend the patents-in-suit are well known and recognized. Under the unique circumstances of this action and the pendency of the Plaintiffs' motion for summary judgment, the declaratory judgment procedure is preferable. It offers a far speedier and potentially less risky and protracted route to a resolution of the direct and fundamental issues. See Elecs. for Imaging, 394 F.3d at 1346.

For the foregoing reasons, the Plaintiffs possess the necessary standing to bring their claims against the Defendants.

VI. JURISDICTION EXISTS OVER THE DIRECTORS

The Defendants have moved to dismiss the Directors as defendants, pursuant to Fed. R. Civ. P. 12(b)(2), for lack of personal jurisdiction. In considering this challenge to personal jurisdiction, Federal Circuit law applies because the jurisdictional issue is "intimately involved with the substance of the patent laws." Autogenomics, Inc. v. Oxford Gene Tech. Ltd., 566 F.3d 1012, 1016 (Fed. Cir. 2009) (quoting Avocent

Huntsville Corp. v. Aten Int'l Co., 552 F.3d 1324, 1328 (Fed. Cir. 2008).

"In the procedural posture of a motion to dismiss, a district court must accept the uncontroverted allegations in the plaintiff's complaint as true and resolve any factual conflicts in the affidavits in the plaintiff's favor." Elecs. for Imaging, 340 F.3d at 1349 (internal citations omitted). Furthermore, because discovery has not yet been conducted, the Plaintiffs need only make a prima facie showing that the Directors are subject to personal jurisdiction. Avocent, 552 F.3d at 1329; Elecs. for Imaging, 340 F.3d at 1349.

"Determining whether personal jurisdiction exists over an out-of-state defendant involves two inquiries: whether a forum state's long-arm statute permits service of process, and whether the assertion of personal jurisdiction would violate due process." Avocent, 552 F.3d at 1329 (quoting Inamed Corp. v. Kuzmak, 249 F.3d 1356, 1359 (Fed. Cir. 2001)). "[D]ue process requires only that in order to subject a defendant to a judgment in personam, if he be not present within the territory of the forum, he have certain minimum contacts with it such that the maintenance of the

suit does not offend traditional notions of fair play and substantial justice." Int'l Shoe Co. v. Washington, 326 U.S. 310, 316 (1945) (internal quotations omitted).

The Supreme Court has distinguished between "general" and "specific" forms of personal jurisdiction. General jurisdiction requires that a defendant have "continuous and systematic" contacts with the forum state. Helicopteros Nacionales de Columbia, S.A. v. Hall, 466 U.S. 408, 415-16 (1984). Minimum contacts establishing specific jurisdiction exist where "the defendant has purposefully directed his activities at residents of the forum and the litigation results from alleged injuries that arise out of or relate to those activities." Burger King Corp. v. Rudzewicz, 471 U.S. 462, 472-73 (1985) (internal quotes and citations omitted). "Once it has been decided that a defendant purposefully established minimum contacts within the forum State, these contacts may be considered in light of other factors to determine whether the assertion of personal jurisdiction would comport with 'fair play and substantial justice.'" Id. (quoting Int'l Shoe, 326 U.S. at 320). Relevant factors include "'the burden on the defendant,' 'the forum State's interest in adjudicating the dispute,' 'the plaintiff's interest in obtaining convenient

and effective relief,' 'the interstate judicial system's interest in obtaining the most efficient resolution of controversies,' and the 'shared interest of the several States in furthering fundamental substantive social policies.'" Id. at 477 (quoting World-Wide Volkswagen Corp. v. Woodson, 444 U.S. 286, 292 (1980)).

In an action seeking a declaratory judgment of patent invalidity, the Federal Circuit has held that specific jurisdiction exists if "(1) the defendant purposefully directed its activities at residents of the forum, (2) the claim arises out of or relates to those activities, and (3) the assertion of personal jurisdiction is reasonable and fair." Breckenridge Pharm., Inc. v. Metabolite Labs, Inc., 444 F.3d 1356, 1363 (Fed. Cir. 2006). "The first two factors correspond with the 'minimum contacts' prong of the International Shoe analysis, and the third factor corresponds with the 'fair play and substantial justice' prong of the analysis." Inamed, 249 F.3d at 1360. With respect to the last prong, the burden of proof is on the defendant, which must "present a compelling case that the presence of some other considerations would render jurisdiction unreasonable." Burger King, 471 U.S. at 476-77.

The Plaintiffs assert claims against the Directors not in their individual capacities, but in their capacity as state officials, pursuant to Ex parte Young, 209 U.S. 123 (1908). The threshold question is whether, for purposes of the personal jurisdiction analysis, the contacts of the Directors as individuals or as state officials should be examined.

Under Ex parte Young, state officials are treated as state actors for all but Eleventh Amendment sovereign immunity issues, regardless of whether the conduct in question is authorized by state law. See Florida Dep't of State v. Treasure Salvos, Inc., 458 U.S. 670, 697 (1982) (suit for relief against a state officer is not barred by the Eleventh Amendment); Home Tel. & Tel. v. Los Angeles, 227 U.S. 278, 282-85 (1913) (officer sued in his official capacity treated as state actor for 14th Amendment purposes). As a result, an official capacity action is, in all but name, a suit against the governmental entity. Kentucky v. Graham, 473 U.S. 159, 165-66 (1985) ("Official capacity suits . . . 'generally represent only another way of pleading an action against an entity of which an officer is an agent.'" (quoting Monell v. N.Y. City Dep't of Social

Servs., 436 U.S. 658, 690 n.55 (1978))); see also Will v. Mich. Dep't of State Police, 491 U.S. 58, 71 (1989) ("[A] suit against a state official in his or her official capacity is not a suit against the official but rather is a suit against the official's office. As such, it is no different from a suit against the State itself." (internal citations omitted)). Consistent with these principles, official capacity defendants may assert only those defenses available to the governmental entity, rather than those available to the defendant as an individual. Graham, 473 U.S. at 165-66; see also Will, 491 U.S. at 71.[22]

When confronted with the issue of specific personal jurisdiction[23] over a non-forum state official, courts routinely examine the contacts of the state officials in their capacity as representatives of the state, rather than their contacts with the forum in their individual capacity. See, e.g., Stroman Realty, Inc. v. Wercinski, 513 F.3d 476, 484 (5th Cir. 2008) (examining

[22] The treatment of state officials sued in their official capacities by the Federal Rules of Civil Procedure reflects this conception of official capacity suits. Those officials need not be identified by name; they are automatically replaced as parties by their successors; and any relief granted is automatically binding not just on the named individual but on his or her successor. See Fed. R. Civ. P. 17(d), 25(d); Hafer v. Melo, 502 U.S. 21, 25 (1991).

[23] Because specific personal jurisdiction exists over the Directors, Plaintiffs' general personal jurisdiction arguments are not addressed here.

extent of defendant's contact with forum as a representative of the state of Arizona);[24] Grand River Enters. Six Nations, Ltd. v. Pryor, 425 F.3d 158, 166 & n.2 (2d Cir. 2005) (analyzing contacts of state attorneys general with New York as representatives of their states).

The Defendants rely on Great Western United Corp. v. Kidwell, 577 F.2d 1256 (5th Cir. 1978), rev'd on other grounds by Leroy v. Great Western United Corp., 443 U.S. 173 (1979), for their assertion that the jurisdictional analysis properly focuses on the contacts of the Directors as individuals with New York. In Great Western, the Court of Appeals considered whether a court in the Northern District of Texas could assert personal jurisdiction over Idaho officials enforcing an Idaho law that had "substantial consequences" in the forum. Great Western, 557 F.2d at 1265, 1267. The Defendants argue that the Fifth Circuit's opinion established that because a state

[24] Defendants cite language in Stroman which they assert refutes Plaintiffs' position. See Defs.' Mem. of Law in Opp. to Pls.' Mot. to Conduct Jurisdictional Disc. at 4 (citing Stroman, 513 F.3d at 485 ("Even if the State of Arizona itself - as a sovereign state, subject to Eleventh Amendment protections - derived a benefit from any 'effects' in Texas generated by the action of the Commissioner, the benefit does not run to those officials in their individual capacity, stripped of their sovereign immunity cloak.")). The cited language, however, in addition to being dicta, is taken from the discussion of whether a "commercial benefit" accrued to the state. It does not establish that the contacts of the official's department are not imputed to her as an official defendant for purposes of personal jurisdiction.

cannot authorize unconstitutional action, a suit for injunctive relief against a state official in his official capacity cannot be viewed as a suit against the state. Instead, it must be viewed as a suit against the official as a private individual, and the contacts to be examined for purposes of personal jurisdiction must be the contacts of the defendant as an individual, rather than as an extension of the state.

The discussion in Great Western cited by the Defendants, however, did not address the question of personal jurisdiction. Instead, the Fifth Circuit considered only the narrow issue of whether the Idaho official was immune from suit outside of Idaho. See id. at 1265 ("Initially McEldowney contends that his status as a state official means that even though he may be sued under Ex Parte Young . . . he may not be sued outside Idaho without his consent." (citation omitted)).[25] In contrast, when the court turned to the issue of "whether due process permits a court in Texas to exercise jurisdiction over the Idaho official who has enforced the Idaho takeover law

[25] To the extent the Fifth Circuit's discussion may be viewed more broadly as establishing that a state official sued in his official capacity should be treated as an individual defendant, such a holding is at odds with subsequent Supreme Court caselaw. See Hafer, 502 U.S. at 26; Will, 491 U.S. at 71; Graham, 473 U.S. at 165-66.

[against a Texas corporation]," id. at 1266, the Fifth Circuit examined the actions of the defendants as representatives of the state, not as individual defendants. See, e.g., id. at 1267 (evaluating defendants' contacts with the forum by examining activities relating to the enforcement of the Idaho takeover statute). On the basis of those contacts, the court concluded that exercising personal jurisdiction over the Idaho officials pursuant to the Texas long arm statute did not violate considerations of due process. Id. at 1266.

The Defendants also rely on Pennington Seed, Inc. v. Produce Exch. No. 299, 457 F.3d 1334 (Fed. Cir. 2006). There, the Federal Circuit's opinion contained no discussion about the proper analysis for considering a state official's contacts with a forum for personal jurisdiction purposes, instead finding that there were no allegations that the university officials had the necessary contacts with the forum. Id. at 1344. The court's observation concerning the location of the officials' residences was made only in passing to note that even that fact failed to establish purposeful activity directed to the forum. Id.

In light of the foregoing, the question of jurisdiction over the Directors should be resolved based upon the Directors' contacts, as representatives of the state, with New York.

Under New York C.P.L.R. § 302(a)(1), specific jurisdiction exists where a defendant "transacts any business within the state or contracts anywhere to supply goods or services in the state." A party "transacts business" when it "purposefully avails [itself] of the privilege of conducting activities within [New York], thus invoking the benefits and protections of its laws." McKee Elec. Co. v. Rauland-Borg Corp., 20 N.Y.2d 377, 382 (1967) (citation omitted). Here, the Directors have entered into an exclusive license agreement that permits Myriad to market the UURF's products and services in New York and creates continuing obligations for UURF.[26] As a result, the Directors have purposefully availed themselves of the privilege of conducting business in New York. Because the claims in this case are directly related to that license agreement and to Defendants' patent enforcement activities that have occurred in New York, the requisite "articulable nexus" between the cause of action and the business

[26] See infra.

activity is present. See, e.g., Credit Lyonais Sec. (U.S.A.), Inc. v. Alcantara, 183 F.3d 151, 153 (2d Cir. 1999). Consequently, specific personal jurisdiction over the Directors exists under New York's long arm statute. See N.Y. C.P.L.R. § 302(a)(1) (2008).

The exercise of specific personal jurisdiction over the Directors also comports with considerations of due process. The Federal Circuit has established that in the context of an action seeking a declaration of patent invalidity, due process considerations are satisfied when the defendants have (1) engaged in cease-and-desist efforts directed to parties in the forum state or attempted to license the patents at issue in the forum state;[27] and (2) entered into an exclusive license agreement with an entity that markets and sells its products and services in the forum state. See Breckenridge, 444 F.3d at 1366; see also Avocent, 552 F.3d at 1333-35; Akro Corp. v. Luker, 45 F.3d 1541, 1546 (Fed Cir. 1995); Genetic Implant Sys. v. Core-Vent Corp., 123 F.3d 1455, 1458-59 (Fed. Cir. 1997). The

[27] Although Defendants appear to assert that only cease-and-desist letters sent to a party in the forum may be relied upon to establish subject matter jurisdiction, the Federal Circuit has stated that offers to license may also serve as the requisite first point of contact with the forum. See Breckenridge, 444 F.3d at 1366 ("Thus, the crux of the due process inquiry should focus first on whether the defendant has had contacts with parties in the forum state beyond the sending of cease and desist letters or mere attempts to license the patent at issue there.").

critical requirement for purposes of establishing due process is that the license agreement impose continuing obligations on the patentee, such as the right to enforce or defend the patents, so that the patentee maintains an ongoing relationship with the licensee operating within the forum that goes beyond the mere receipt of royalty income. See Breckenridge, 444 F.3d at 1366. The personal jurisdiction analysis of the Directors' contacts with the forum state thus turns on "the defendant's relationship with its exclusive licensee." Id. at 1365; see also Akro, 45 F.3d at 1546-47.

Here, the Defendants have attempted to license the patents-in-suit to Dr. Ostrer, a resident of New York.[28] See Ostrer Decl. ¶ 7 & Ex. 2. They have also caused or participated in direct in-person cease-and-desist efforts that occurred in New York. Kazazian Decl. ¶ 6. In addition, the agreement between Myriad and UURF creates ongoing obligations on the part of the UURF beyond the mere receipt of royalty payments. As set forth in the standard licensing term sheet, UURF's policy is to retain the right to enforce licensed patents and to initiate proceedings

[28] While the offer to license made to Dr. Ostrer was sent on Myriad Genetics' letterhead, Plaintiffs assert that Myriad and UURF acted together in asserting the rights granted by the patents-in-suit. See, e.g., Compl. ¶¶ 29, 49.

regarding them. Ravicher Aff. Ex. 7. Myriad, of course, has a similar ability to take action enforcing the patents as demonstrated by its actions to enforce the patents-in-suit.[29] See supra. Both UURF and Myriad appear to have obligations relating to the enforcement and maintenance of the patents at issue in this lawsuit which establishes that the Directors have purposefully directed their activities at New York as a matter of law.[30] See, e.g., Avocent, 55 F.3d at 1336 ("[W]hen the patentee enters into an exclusive license or other obligation relating to the exploitation of the patent by such licensee or contracting party in the forum . . . the patentee may be said to purposefully avail itself of the forum and to engage in activity that relates to the validity and enforceability of the patent."); Breckenridge, 444 F.3d at 1366; Akro, 45 F.3d at 1546.

In addition, the claims in this suit directly relate to the license agreement between the Defendants and their efforts to enforce the patents. See, e.g., Akro, 45 F.3d at 1548-49 ("[The patentee's] exclusive license agreement with [the plaintiff's] local competitor Pretty

[29] Neither party contests that Myriad purposefully engages in business in New York, where it both solicits and sells a significant volume of its testing services.

[30] In addition, both the Directors and Myriad are represented jointly by counsel, further suggesting the existence of an ongoing relationship between the two entities. See Breckenridge, 444 F.3d at 1367.

Products undoubtedly relates to [the plaintiff's] challenge to the validity and enforceability of the '602 patent."). Finally, the Defendants have not presented other considerations that would render it unfair or unjust for the Court to exercise jurisdiction over them.

Consequently, the Court's exercise of personal jurisdiction over the Directors satisfies the requirements of due process.

VII. THE ALLEGATIONS OF CONSTITUTIONAL VIOLATIONS ARE ADEQUATE

In ruling on a motion to dismiss made pursuant to Rule 12(b)(6), the Court must accept all well-pleaded factual allegations in the complaint as true. Erickson v. Pardus, 551 U.S. 89, 94 (2007) (citing Bell Atl. Corp. v. Twombly, 550 U.S. 544, 555 (2007)). In addition, the Court must "construe[] the complaint liberally" and "draw[] all reasonable inferences in the plaintiff's favor." Chambers v. Time Warner, Inc., 282 F.3d 147, 152 (2d Cir. 2002) (citing Gregory v. Daly, 243 F.3d 687, 691 (2d Cir. 2001)). The question before the court "is not whether a plaintiff will ultimately prevail but whether the claimant is

entitled to offer evidence to support the claims." Villager Pond, Inc. v. Town of Darien, 56 F.3d 375, 378 (2d Cir. 1995) (quoting Scheuer v. Rhodes, 416 U.S. 232, 235-36 (1974)). Consequently, the complaint should not be dismissed on a motion for judgment on the pleadings unless it appears beyond doubt that the plaintiff can prove no set of facts in support of its claims that would entitle it to the relief it seeks. Faconti v. Potter, 242 Fed. App'x 775, 777 (2d Cir. 2007).

The USPTO challenges the sufficiency of Plaintiffs' complaint in light of the Supreme Court's recent holding in Ashcroft v. Iqbal, 129 S.Ct. 1937 (2009). Iqbal set forth "[t]wo working principles" to guide a court's analysis of a complaint's sufficiency. Id. at 1949. "First, the tenet that a court must accept as true all of the allegations contained in a complaint is inapplicable to legal conclusions." Id. "Second, only a complaint that states a plausible claim for relief survives a motion to dismiss." Id. at 1950.

In this case, the Plaintiffs have pled sufficient factual allegations to satisfy the standard set forth in Iqbal. The Complaint alleges the existence of a specific,

written policy for the patenting of genes and the parameters of the policy. Compl. ¶ 50. The policy, contained in the Federal Register, Utility Examination Guidelines, 66 Fed. Reg. 1092 (Jan. 5, 2001), is alleged by the Plaintiffs to be applied to a series of specific patents and patent claims. Compl. passim. The Plaintiffs describe each application of the policy in considerable detail. See, e.g., Compl. ¶¶ 55-80. Similar allegations and specificity apply to the Plaintiffs' allegations of the USPTO's practices. See, e.g., Compl. ¶¶ 53-54.

The Complaint further alleges that the information encoded in the *BRCA1/2* genetic sequences, rather than being the result of an inventive process, exists in nature. See Compl. ¶¶ 34, 46, 51, 55-60. The Complaint also alleges that the existence of certain mutations in *BRCA1/2* and their correlation with an increased risk of breast and/or ovarian cancer constitutes nothing more than a naturally occurring phenomenon. See Compl. ¶¶ 61-80. Based on these factual allegations, the Plaintiffs assert that the patents-in-suit grant Myriad ownership rights over products of nature, laws of nature, natural phenomena, abstract ideas, and basic human knowledge and thought in violation of the First Amendment's

protections over freedom of thought. Compl. ¶¶ 52, 54. In addition, the Plaintiffs assert that Myriad's ownership of correlations between certain *BRCA1/2* mutations and an increased risk of breast and/or ovarian cancer has inhibited further research on *BRCA1/2* as well as genes that interact with *BRCA1/2*. See, e.g., Compl. ¶¶ 96-98, 101. As a result, the patents-in-suit are alleged to violate Article I, section 8, clause 8 of the Constitution which directs Congress to "promote the Progress of Science and useful Arts . . . ." Compl. ¶¶ 52, 54.

The facts alleged in the Complaint are plausible, specific, and form a sufficient basis for Plaintiff's legal arguments. Consequently, the pleading requirements as set forth in Iqbal are satisfied.

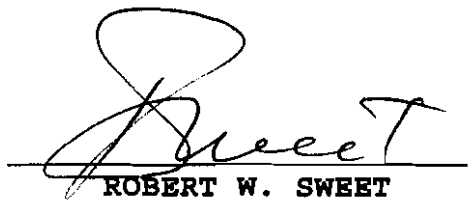
VIII. CONCLUSION

For the reasons stated above, Defendants' motion to dismiss the Complaint is denied.

Defendants' opposition to Plaintiffs' motion for summary judgment will be due December 2, 2009. Plaintiffs' reply will be due on December 9, 2009, and argument will be heard on December 11, 2009, at ten o'clock in the forenoon in Courtroom 18C, unless good cause is shown to alter the date of the submissions.

It is so ordered.

New York, N.Y.
November 1, 2009



ROBERT W. SWEET
U.S.D.J.